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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/660,444

09/11/2003

Andrzej Chanduszeko

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4893

22852

7590

11/23/2009

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

11/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/660,444	<b>Applicant(s)</b> CHANDUSZKO ET AL.	
	<b>Examiner</b> DIANE YABUT	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31,34-37,40-42 and 60-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31,34-37,40-42 and 60-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/08/2009 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 31, 34-35, and 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobles** (U.S. Pub. No. **2002/0045908**) in view of **Ginn** (U.S. Patent No. **6,702,835**).

Nobles discloses introducing into a heart of a patient a delivery member comprising at least a first flexible ("resilient") member **50** or **128** having a first end portion and arms **28** and **32** (first and second flexible members) at a second free end portion, and introducing said second free end portion through the opening of a patent

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foramen ovale **26** (page 6, paragraph 141) by entering the opening from one side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the opposite side prior to introducing a hole through a septal tissue **22**, contacting said first and second flexible members **28, 32** on the opposite side of the septal tissue (Figure 4B), introducing a hole through the septal tissue from the one side to the opposite of the septal tissue, withdrawing said second free end portion of said flexible member from the opposite side (Figures 1-2, 15-16, 34-39). The hole may be introduced through the septal tissue while simultaneously biasing said second free end portion in contact with the tissue to minimize movement, as in Figures 79-80, 103A, in order to "provide mechanical support" to the tissue (paragraph 146). Nobles also discloses an apparatus ("patch") for joining tissue page 25, paragraph 351). After withdrawing the second free end portion of said flexible member, an occlusion device **880** or **890** may be introduced through the hole created by the septal tissue (paragraphs 314-320, Figures 72-73).

Although the flexible member is not spiral-shaped, it would have been obvious to one of ordinary skill in the art to modify Nobles with a spiral-shaped flexible member since coils, spirals, and helical configurations are well known shapes for elements that effectively approximate tissue.

Nobles discloses the claimed invention except for expressly disclosing introducing the delivery member from the right atrial side to a left atrial side, instead of from generally "one side" to the "opposite side" of septal tissue.

Ginn teaches delivering a delivery member to a patent foramen ovale from a right atrial side to the left atrial side (Figures 5A-8B; col. 7, line 60 to col. 8, line 9). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Nobles by introducing the delivery member from the right atrial side to a left atrial side, as taught by Ginn, since it was well known in the art for septal occluders to be effectively introduced percutaneously into a peripheral vein, such as a femoral or jugular vein, to be advanced through the vena cava into the right atrium and then advanced beyond the septum wall in the left atrium.

4. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobles** (U.S. Pub. No. **2002/0045908**) in view of **Ginn** (U.S. Patent No. **6,702,835**), as applied to claim 35 above, and further in view of **Sawyer** (U.S. Patent No. **5,749,895**).

Neither Nobles nor Ginn expressly discloses using a tissue welding apparatus. However, use of a tissue welding apparatus is well known in the art, as evidenced by Sawyer (see abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue welding apparatus, as taught by Sawyer, to Nobles and Ginn in order to more effectively ensure a tight occlusion of the PFO defect.

5. Claims 37 and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobles** (U.S. Pub. No. **2002/0045908**) in view of **Ginn** (U.S. Patent No. **6,702,835**) and **Das** (U.S. Patent No. **5,334,217**).

Nobles and Ginn disclose the claimed invention, as discussed in paragraph 3 above, except for the flexible members being hexagonally shaped.

Das teaches a septal closure device and method using flexible members **24C** being introduced into a patent foramen ovale, which are hexagonally shaped (Figure 5C). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Nobles with Das, since it is also a closure method and the hexagonally shaped members provide bends which permit the frame to be collapsed more readily into a delivery catheter (col. 5, line 54 to col. 6, line 6).

6. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobles** (U.S. Pub. No. **2002/0045908**) in view of **Ginn** (U.S. Patent No. **6,702,835**) and **Das** (U.S. Patent No. **5,334,217**), as applied to claim 41 above, and further in view of **Sawyer** (U.S. Patent No. **5,749,895**).

Nobles, Ginn, and Das do not expressly disclose using a tissue welding apparatus. However, use of a tissue welding apparatus is well known in the art, as evidenced by Sawyer (see abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue welding apparatus, as taught by Sawyer, to Nobles, Ginn, and Das in order to more effectively ensure a tight occlusion of the PFO defect.

***Response to Arguments***

7. Applicant's arguments filed 09/08/2009 have been fully considered but they are not persuasive.

8. The applicant generally argues that Nobles does not disclose applying pressure to the suture clasp arms (the "flexible members" recited in the claims) to limit the movement of the tissue as needles simultaneously penetrate the tissue. However, in some embodiments Nobles does disclose that the suture clasp arms (**630, 1410, 1410'**) may be deployed so that they are parallel to the tissue and "provide mechanical support" to the tissue while the needles (**650, 1440, 1440'**) penetrate tissue (see kparagraphs 141 and 146, Figures 4B-4C, 14, 79-80, 103A), and therefore reads on this limitation.

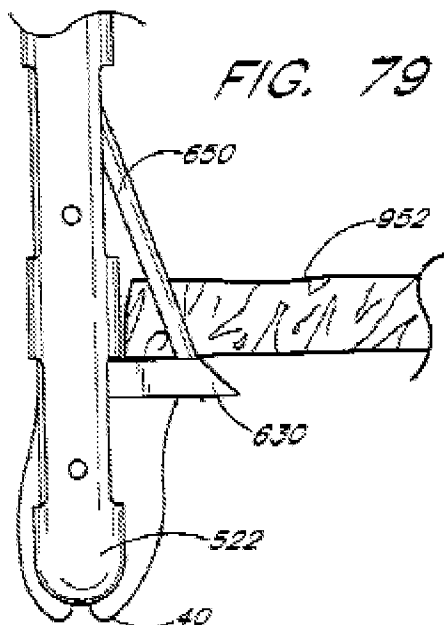
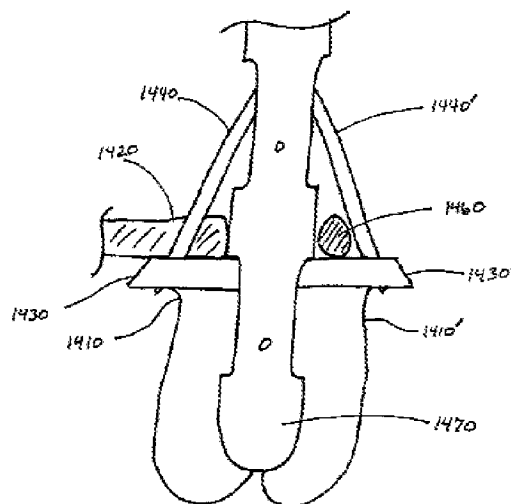


Fig. 103A:



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/  
Primary Examiner, Art Unit 3734

/Diane Yabut/  
Examiner, Art Unit 3734